भारतीय मानक
Indian Standard

IS 17713 : 2023

इन-विट्रो डायग्नोस्टिक (आईवीडी) उपकरण — एलिसा प्लेट रीडर

In-Vitro Diagnostic (IVD) Device — ELISA Plate Reader

ICS 11.100.10

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November 2023 **Price Group 5**

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

FOREWORD

This Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the *In-vitro* Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee had been approved by Medical Equipment and Hospital Planning Division Council.

This standard specifies the general requirements and standard test procedures for Performance Testing of *In-Vitro* Diagnostic (IVD) Instruments — ELISA Plate readers, also known as microplate readers or microplate photometers. These are used to detect biological, chemical or physical events of samples in microtiter plates using absorbance technique.

The composition of the Committee responsible for formulation of the standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed, or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

IN-VITRO DIAGNOSTIC (IVD) DEVICE — ELISA PLATE READER

1 SCOPE

This standard specifies the general requirements and the performance test procedure for the *in-vitro* diagnostic (IVD) instrument — ELISA plate reader also known as microplate reader or photometer. This is used to detect biological, chemical or physical event of sample in microtiter plates.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards.

IS No.		*Title*
IS/ISO 13485 2016	:	Medical devices — Quality management systems — Requirements for regulatory purposes (*first revision*)
IS/ISO 14971 2019	:	Medical devices — Application of risk management to medical devices (*first revision*)
IS 17724		Safety requirements for electrical equipment for measurement, control, and laboratory use:
(Part 1) : 2023		General requirements
(Part 4) : 2023		Particular requirements for *In-vitro* diagnostic IVD medical equipment
IS 17784		Electrical equipment for measurement, control and laboratory use — EMC requirements
(Part 1) : 2023		General requirements
(Part 2) : 2023		Particular requirements for *In-vitro* diagnostic (IVD) medical equipment

3 TERMS AND DEFINITION

3.1 ELISA Plate Reader

This is a device used to measure the biological activity of the sample using absorbance method.

4 DESIGN AND CONSTRUCTION REQUIREMENTS

4.1 The ELISA plate reader works on the principle of absorbance. The device consists of a light source, which is directed towards the microplate with the sample, through the lens. A part of the light is absorbed by the sample and the remaining is transmitted. The transmitted light is filtered by the interference filters and focused on to the photodiodes. The light energy is converted into electrical energy by the photodiode, which in turn is digitized by the microprocessor for the calculation of the absorbance. The calculation of the absorbance takes into consideration the blank and bi-chromatic measurement section.

4.2 The reader shall have minimum 96 wells with a reading capacity of 1 to 96 wells individually.

4.3 The device shall have a variable speed plate shaking capability.

4.4 The reader shall be constructed such that it shall read U, V and flat type wells.

4.5 The device is recommended to have 8 position filter wheels with minimum 4 standard filters.

4.6 The device shall have provision for different types of blanking like air wise and well wise.

4.7 The device shall have the capability of reading 8 or 12 well strip plates.

4.8 The reader shall have internal thermal printer and 5 thermal print rolls supplied along with the unit. An external printer connectivity option is recommended.

4.9 The reader can have other additional constructional features which may vary from model to model depending upon the manufacturer.

4.10 The device shall be treated by a suitable passivation process. The recommended technique shall be electropolishing or by treatment with 10 percent nitric acid solution (v/v) for not less than 30 minutes at a temperature between 10 ºC and 60 ºC. The device shall be rinsed in water and dried in hot air.

5 REQUIREMENTS

5.1 General Requirements

The ELISA plate reader shall comply with the requirements as specified in IS 17724 (Part 1) and IS 17724 (Part 4).

5.2 Electromagnetic Compatibility Requirements

The ELISA plate reader shall comply with the requirements as specified in IS 17784 (Part 1) and IS 17784 (Part 2).

6 PERFORMANCE MEASUREMENT AND QUALIFICATION PROCEDURE

6.1 Resolution

The resolution of the device shall be 0.001 absorbance.

6.2 Photometric Range

The device shall have a photometric range between 0.000 and 3.000 absorbance.

6.3 Light Source

The device shall use appropriate light source like halogen lamp, LED, xenon flash, tungsten halogen light source etc.

6.4 Wavelength

The wavelength shall be in the range of 300 nm to 750 nm.

6.5 Calculation Method

The device shall use any of the calculation modes ABS, cut-off, curve, linear, log and exponent regression, 4 parameter log regression model etc.

6.6 Reading Speed

The reading speed for 96 well plate shall be 10 seconds using single wavelength and up to 40 seconds for multiple wavelengths.

6.7 Storage Requirements

The device shall be provided with internal storage with a capacity to create, edit and run 40 programmable user protocols.

6.8 Accuracy of Microplate Reader

6.8.1 The accuracy of the microplate reader is calculated by the following procedure:

6.8.1.1 The ELISA calibration plate is mounted on the reader. The absorbance is measured at 405 nm, 450 nm, 492 nm, 630 nm wavelength. The absorbance values are recorded. The photometric accuracy shall have a tolerance of ± 2 percent for 0.000 < absorbance < 1.500 and tolerance of ± 3 percent for 1.500 < absorbance < 3.000.

6.9 Precision of Microplate Reader

6.9.1 The precision of the microplate reader is calculated by the following procedure:

6.9.1.1 The ELISA calibration plate is mounted on the reader. The absorbance is measured at 405 nm, 450 nm, 492 nm, 630 nm wavelength. The absorbance values are recorded. The photometric precision shall have a tolerance of ± 2 percent for 0.000 < Absorbance < 1.500 and tolerance of ± 3 percent for 1.500 < Absorbance < 3.000.

6.10 Linearity of Microplate Reader

6.10.1 Linearity is a measure of accuracy over the full range of the device. The linearity of the microplate reader is calculated by the following procedure:

6.10.1.1 The absorbance of at least 5 reference samples that cover the range of the device is measured. The reference measurement for each of the sample is compared with the measured value. The measurement is repeated at least 10 times by the same operator. The average for the range of measurements is calculated. The average measured value for each sample is plotted on y-axis against the reference value on x-axis. The device is linear if the resulting line is approximating a straight line with 45º slope.

7 RISK MANAGEMENT AND QUALITY CONTROL

7.1 The device shall comply with IS/ISO 14971 w.r.t the risk management process for the device.

7.2 The manufacturer of the device shall comply with the quality management system standard IS/ISO 13485.

8 OPERATING MANUAL

The device shall be accompanied with the operating manual with the following information:

a) Instructions for installation;
b) Manual for operation of the device; and
c) Routine maintenance and service procedure.

9 MARKING, LABELLING AND PACKAGING

9.1 The device shall be legibly and indelibly marked at suitable place with the following details:

a) Product name along with the phrase "**for *in-vitro* diagnostic use only**";

b) Name of the manufacturer and address;
c) Country of manufacture;
d) Serial number; and
e) Warning labels.

9.2 The device shall be packed securely with suitable material, to ensure that the risk of damage is minimized during the transportation.

9.3 Proper decontamination procedure shall be followed before packing the device.

9.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

Organization	*Representative(s)*
In Personal Capacity (*E117 first floor Greater Kailash 2, New Delhi, 110048*)	Dr Reba Chabbra **(*Chairperson*)**
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